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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/522,753	03/10/2000	Ronald M. Evans	SALK1510-3	4924

7590 07/01/2002

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EXAMINER

LOEB, BRONWEN

ART UNIT PAPER NUMBER

1636

DATE MAILED: 07/01/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/522,753

Applicant(s)

EVANS ET AL.

Examiner

Bronwen M. Loeb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 & 16 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-37 is/are pending in the application.
- 4a) Of the above claim(s) 26-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 April 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

### **DETAILED ACTION**

This action is in response to the amendments filed 10 April 2002 and 16 April 2002. The amendment filed 10 April 2002 amended claims 1, 3, 5, 6, 9, 10, 12, 14, 15 and 23 and cancelled claim 2. The amendment filed 16 April 2002 was in response to the sequence compliance.

Claims 1 and 3-37 are pending.

### ***Oath/Declaration***

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

There is no signature for Inventor Chan.

Applicant acknowledged the defective oath/declaration in the amendment filed 10 April 2002 and stated that this would be corrected under separate cover. To date, the corrected oath/declaration has not been received.

### ***Election/Restrictions***

2. Claims 26-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

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linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

### ***Sequence Compliance***

3. The sequence listing and the computer readable file submitted 16 April 2002 have placed the specification in compliance with 37 CFR 1.821-1.825.

### ***Drawings***

4. The corrected or substitute drawings were received on 10 April 2002. These drawings are acceptable with respect to Figures 4, 6C and 12C. Substitute Figures 5A and 9, however, are only marginally improved. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Response to Amendment***

5. The terminal disclaimer filed on 10 April 2002 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Number 08/522,726 has been reviewed and is accepted. The terminal disclaimer has been recorded.

6. The rejection of claims 1-7, 19, 21 and 22 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 7 of

copending Application No. 08/522,726 has been withdrawn in view of the terminal disclaimer filed 10 April 2002.

The rejection of claims 1, 3, 5, 6, 8, 11, 16 and 19-22 under 35 U.S.C. §112, first paragraph, scope of enablement, has been withdrawn in view of Applicant's amendment.

The rejection of claims 4, 7, 9, 10 and 12 under 35 U.S.C. §112, first paragraph, scope of enablement, has been withdrawn in view of Applicant's amendment.

The rejection of claims 1, 2, 4, 6-14 and 16-25 under 35 U.S.C. §112, second paragraph, as being indefinite has been withdrawn in view of Applicant's amendment.

7. Claims 1, 3, 5, 6, 8, 11 and 19-22 stand rejected under 35 U.S.C. §112, first paragraph, for insufficient written description for reasons of record and as further discussed below.

Claims 4, 7, 9, 10 and 12 stand rejected under 35 U.S.C. §112, first paragraph, for insufficient written description for reasons of record and as further discussed below.

Claims 3, 5 and 16, and amended claim 14 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reasons of record and as further discussed below.

8. New grounds of rejection, necessitated by Applicant's amendment, are presented below.

***Response to Arguments***

9. With respect to the rejection of claims 1, 3, 5, 6, 8, 11 and 19-22 under 35 U.S.C. §112, first paragraph, for insufficient written description, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that the members of the claimed genus share structural homology across distinct regions of their N-terminal domains and mentions the RD1 region (amino acids 1-312) and the SANT region (amino acids 312-668). Applicant notes that the human and mouse alpha SMRT members are virtually identical across their entire lengths. Applicant further asserts that the conserved regions of identity within the N-terminal domain provide regions that are related to the conserved co-repression function exhibited by all members of the family. These arguments are not persuasive for at least the following reasons. Applicant appears to assume that shared homology must correlate to shared function however there is no structure-function analysis presented to support this assumption. While there are regions of shared homology there is no disclosure of what specific amino acids within these regions are responsible for the repression function. The observation that the mouse and human SMRT alpha members are nearly identical throughout their sequence certainly does not guarantee that any other species of the genus would also be nearly identical. As noted in the previous action, the isoforms of these nearly identical homologs have extremely different sequences deleted. Thus, their nearly identical sequence cannot be extrapolated into predicting what isoforms will result. Furthermore, there is no detailed structure-function analysis regarding any regions of homology in the C-terminal (which

is involved in interaction with the ligand binding domain of RAR and TR). Thus, there is no teaching of what specific amino acids dictate the binding specificity for either RAR or TR, not to mention all the other members of the steroid/thyroid hormone superfamily of receptors. As mentioned in the previous action, the *Drosophila* SMRTER sequence has significant regions of homology with SMRT and N-CoR and yet is not considered a SMRT family member; there is no disclosure of what specific sequences set SMRTER apart from the SMRT genus functionally. For at least these reasons, the rejection is maintained.

10. With respect to the rejection of claims 4, 7, 9, 10 and 12 under 35 U.S.C. §112, first paragraph, for insufficient written description, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that the term "conservative variations" is commonly used in the art to represent substitutions encoding amino acids such that the tertiary structure of the protein is not substantially altered and that the specification provides exemplary conservative substitutions. While these arguments are true they are not persuasive for the following reasons. This information is meaningless without detailed structure-function analysis for the known members of the genus from which one might understand where such conservative substitutions could exist and still maintain the structure and function of the protein. There is no disclosure of the amino acids which form the hydrophobic core which is essential to the proper tertiary structure nor is there any disclosure of the specific amino acids that underlie the repression function or the interaction with either RAR or TR. Absent this structure-function correlation, the

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specification does not provide adequate written description for the many species encompassed by the claimed genus. The rejection is maintained.

11. With respect to the rejection of claims 3, 5 and 16, and amended claim 14, under 35 U.S.C. 112, second paragraph, as being indefinite, Applicant's arguments have been fully considered but are deemed not persuasive.

Applicant argues that "hybridizes under stringent conditions" is so commonly accepted in the art that it no longer requires a definition. This is not persuasive as there are a wide variety of conditions that might be considered stringent by some skilled artisans and not stringent by other skilled artisans. Lacking a definition in the specification, this term is clearly indefinite and the metes and bounds of the claims cannot be determined. The rejection is maintained.

### **New Grounds of Rejection**

#### ***Claim Rejections - 35 USC § 112***

12. The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 9, 10 rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 10 and 12 are vague and indefinite for reciting "substantially the same". This is not a term of art and is not defined in the specification.



### ***Conclusion***

Claims 1 and 3-25 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from

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10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Bronwen M. Loeb, Ph.D.  
Patent Examiner  
Art Unit 1636

June 30, 2002



**JAMES KETTER  
PRIMARY EXAMINER**